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IN THE

Supreme Court of the United States

October Term, 1973

No. 73 1700

NATIONAL NUTRITIONAL FOODS ASSOCIATION and SOLGAR CO., INC.,

Petitioners,

against

ALEXANDER M. SCHMIDT, Commissioner of Food and Drugs, and CASPAR W. WEINBERGER, Secretary of Health, Education and Welfare,

Respondents.

PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT

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NATIONAL NUTRITIONAL FOODS ASSOCIATION and SOLGAR CO., INC.,

Petitioners,

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ALEXANDER M. SCHMIDT, Commissioner of Food and Drugs, and CASPAR W. WEINBERGER, Secretary of Health, Education and Welfare,

Respondents.

PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT

Petitioners pray that a writ of certiorari issue to review the judgment of the United States Court of Appeals for the Second Circuit, entered in the above entitled case on March 26, 1974.

Citations to Opinions Below

The opinion of the District Court dismissing the complaint is set forth in Appendix A, *infra*, and is officially reported at 367 F.Supp. 889 (S.D.N.Y. 1973). The judgment of the Court of Appeals affirming the decision of the District Court is set forth in Appendix B, *infra*. The opinion upon which such affirmance was based is set forth in Appendix C, *infra*, and is officially reported at 491 F.2d 1141 (2d Cir. 1974).

Jurisdiction

The judgment of the Court of Appeals was entered on March 26, 1974 (Appendix B, *infra*, page B1). The jurisdiction of this Court is invoked under 28 U.S.C. §1254(1).

Questions Presented

1. Whether the rule of law established by this Court in *Morgan* v. *United States*, 298 U.S. 468 (1936) is still viable so as to require the administrative officer, designated by statute to render a decision, to personally "consider and appraise" the record and argument prior to promulgating orders based on an evidentiary public hearing.

2. Whether the promulgation of orders based on an evidentiary public hearing can be challenged in accordance with the decision of this Court in *Morgan* v. *United States*, *supra*, on the basis of a strong showing that the administrative officer responsible for such orders did not comply with his duty to personally consider and appraise the record and objections before him prior to signing such orders.

3. Whether a District Court has jurisdiction to entertain a procedural challenge to administrative orders issued pursuant to the Federal Food, Drug, & Cosmetic Act, 21 U.S.C. §§371(e) and (f), where the procedural defect is not apparent in the administrative record and where the statutory review procedure in the Court of Appeals is limited to a review of such record.

Statutes Involved

The statutory provisions of the Federal Food, Drug and Cosmetic Act involved herein are 21 U.S.C. §§371(e) and (f). Also involved are provisions of the Administra-

tive Procedure Act appearing at 5 U.S.C. §§703 and 706, as well as the statutory jurisdictional provisions in 28 U.S.C. §§1331(a) and 1337. They are printed in Appendix D, *infra*.

Statement

The regulations which are the subject of this petition have been under consideration by the Food and Drug Administration for a period of more than 11 years. The detailed and complex history of these regulations is set forth in the opinions of the District Court and the Court of Appeals. It is sufficient to note here that on July 12, 1973, Alexander M. Schmidt was sworn in as Commissioner of Food and Drugs. During the following 13-day period (which included two weekends), the newly appointed Commissioner signed and caused to be published at least a total of 33 items comprising 14 final regulations, 13 proposed regulations and 6 notices. According to the accompanying statements made in the Federal Register, these items purportedly involved the review by the Commissioner of thousands of documents containing objections submitted to the agency in connection with all of the aforementioned final regulations, as well as very numerous conclusions and determinations covering a wide variety of technical subjects and proposals.

Included in the above total were the two final orders at issue herein, signed by respondent Alexander M. Schmidt on July 25, 1973 and published in the Federal Register on August 2, 1973 (38 F.R. 20708-20718, 20730-20740) [hereinafter referred to as Dietary Supplement Regulations]. These two orders were the purported end-product of the longest administrative proceedings ever conducted by the Food and Drug Administration. Two years of public hearings were held in this matter and the transcript of the

proceedings consists of over 32,000 pages of testimony, thousands of additional pages of documentary exhibits, a lengthy report by the Hearing Examiner, over 1,000 pages of formal objections and exceptions, and 20,000 letters.

In what appears to be an effort to demonstrate compliance by the new Commissioner with his duty to consider the massive record before him, each of the two final orders states:

> "Having considered the evidence received at the hearing, the Hearing Examiner's Report, and all the exceptions and written arguments which were filed, the Commissioner, pursuant to the Federal Food, Drug, and Cosmetic Act . . . issues the following findings of fact, conclusions and final order. . . ." 38 F.R. 20712 and 38 F.R. 20734 (August 2, 1973).

Similar statements are made by the Commissioner with respect to the other final orders promulgated during the above-mentioned 13-day period and throughout all of the regulations, proposals, and notices signed into effect during this period there are routine assertions of varying degrees of purported decision-making by the new Commissioner.

Shortly after the promulgation of the Dietary Supplement Regulations, 15 petitions, including one by the petitioners in this Court, were filed in various United States Circuit Court of Appeals, and were ultimately consolidated in the Second Circuit (*NNFA and Solgar Co., Inc., et al.* v. *Food and Drug Administration, et al.*, Docket No. 73-2129, *et al.*). In addition, petitioners herein brought the instant case in the United States District Court for the Southern District of New York seeking prohibitory and mandatory injunctive relief with respect to procedural errors not

otherwise apparent in the record of the Dietary Supplement Regulations. Jurisdiction in the District Court was based on 28 U.S.C. §§1331(a) and 1337. Appendix D, *infra*, page D5.

The complaint alleges the above-noted massive nature of the proceedings leading up to the promulgation of the Dietary Supplement Regulations as well as the other purported activities by the new Commissioner within the relevant 13-day period, all of which are a matter of public record. It is further alleged upon information and belief that the new Commissioner did not and could not have exercised his independent judgment and discretion prior to the promulgation of the Dietary Supplement Regulations and that the decision with respect to such regulations was not and could not have been made by him.

Petitioners moved promptly in the District Court to take the deposition of respondent Alexander M. Schmidt with respect to his actions or non-action during the relevant 13-day period. Respondents forestalled such inquiry, however by moving to dismiss the complaint for lack of jurisdiction and for failure to state a cause of action. The District Court dismissed the complaint for lack of jurisdiction, holding that such a challenge to the regulations could only be made in a Court of Appeals.

An appeal was taken from said decision, but proceedings thereon were deferred while a direct application was made in the aforementioned pending consolidated cases in the Court of Appeals for the Second Circuit for leave to supplement the record in that Court by taking testimony and presenting evidence of the new Commissioner's failure to personally render the decision with respect to the Dietary Supplement Regulations. The application was denied in an opinion dated February 1, 1974 (Appendix C, *infra*).

The decision of the Court of Appeals appeared to agree with the prior decision of the District Court as to jurisdiction and in addition in effect ruled that the facts alleged in the complaint failed to state a cause of action. Petitioners, therefore, resumed their prosecution of the appeal from the decision of the District Court by moving for an affirmance of said decision on the basis of the Court of Appeals' ruling.

Petitioners noted that they sought such an affirmance for the purpose of making the instant petition for a writ of certiorari. In response to said motion, the Court of Appeals did formally affirm the decision of the District Court by an order dated March 26, 1974 (Appendix B, *infra*).

Reasons for Granting the Writ

Petitioners respectfully submit that certiorari should be granted herein to resolve important and recurring questions basic to the procedural decision-making process of all administrative agencies. The decision of the Court of Appeals is contrary to the decisions of this Court with respect to the nature of (a) the duty of administrative officials who are personally responsible for rendering a decision with respect to orders based on statutory hearing requirements and (b) the remedies available to litigants to enforce such duty.

Petitioners seek to resolve the interpretation and distinction between two long-standing decisions of this Court which have received contrary interpretations by two United States Court of Appeals. In addition, the Court is presented with recurring questions of the proper scope of the jurisdiction of the United States District Courts to review agency action under the Federal Food, Drug, and Cosmetic Act.

I. This case involves regulations making numerous factual determinations required by statute to be based solely on substantial evidence adduced at a public hearing. 21 U.S.C. §371(e)(3). The statute and regulations require the Commissioner of Food and Drugs "to himself make the actual decision." *Williapoint Oysters* v. *Ewing*, 174 F.2d 676 at 696 (9th Cir. 1950); 21 U.S.C. §371(e), 21 CFR 2.98. The nature of this duty was spelled out in *Morgan* v. *United States*, 298 U.S. 468 (1936) [*Morgan I*], which, while allowing reliance on subordinates to gather and sift evidence, required the responsible officer to "consider and appraise" the evidence and argument because "the one who decides must hear." 298 U.S. 480-482. This personal duty was reaffirmed by this Court in the second *Morgan* case, 304 U.S. 1 at 23 (1938) [*Morgan II*].

The Court of Appeals herein, while agreeing that the respondent Commissioner could not have complied with the duty spelled out in *Morgan I*, expounds a new rule of law by saying that it was sufficient for the Commissioner to have read the "preambles" to the orders signed during this period and that he "could have done this even in the limited time available . . . although we do not envy him the task." Appendix C, *infra*, pages C9-10, 491 F.2d at 1146.

Petitioners respectfully submit that such an unlikely reading of the "preambles" does not in any event comply with the requirement that the officer "consider and appraise" the evidence and argument before him. With respect to all of the most basic issues in the administrative hearings the "preambles" are replete with statements, such as the following:

> "The Commissioner has carefully reconsidered the Hearing Record, and reiterates his conclusion that it is not nutritionally sound . . . to permit inclusion of these ingredients in dietary supplements or other

> form of foods for special dietary use." 38 F.R. 20711 (August 2, 1973).
>
> "The Commissioner has reviewed the record and finds no persuasive justification for additional combinations at this time." 38 F.R. 20731 (August 2, 1973).

In sum, the Court of Appeals would encourage the mere signing of recommended orders "on the basis of summaries of evidence and findings slanted in each case to support those recommendations." *Crouse Cartage Co.* v. *United States*, 343 F.Supp. 1133 at 1139-1140 (N.D. Iowa, 1972). Surely, the classic formulation in *Morgan I* requires more in terms of a consideration of the arguments presented by affected members of the public. No public purpose or need was served by having the new Commissioner sign numerous long-pending matters into effect during his first 13 days in office. The interests of justice herein and the public interest in responsible administrative decision-making warrant a reaffirmation by this Court of the principles established in *Morgan I*.*

II. The Court of Appeals' ruling that petitioners cannot challenge the Commissioner's apparent failure to personally consider the record and exceptions is based on its view that this Court's decision in *United States* v. *Morgan*, 313 U.S. 409 (1941) [*Morgan IV*] involved a "retreat" from the principles established by the Court in *Morgan I*. A careful reading of the *Morgan* cases (including *Morgan* v. *United States*, 304 U.S. 1 (1938) [*Morgan II*]) shows that the circumstances surrounding

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* It should also be noted that the legislative history of the Federal Food, Drug and Cosmetic Act shows that at the time of the enactment of the statute in 1938, it was the express intent of Congress to incorporate the requirements of the first two *Morgan* cases into the hearing procedures under the Act. See 83 Congressional Record 9096 (June 13, 1938).

the examination of the administrative officials was markedly different in *Morgan I* and *Morgan II* from the subsequent examination disapproved in *Morgan IV*. See also *Singer* v. *NLRB*, 329 F.2d 200, 206-208 (4th Cir. 1964) where these cases are properly distinguished. In essence, the instant case does not involve an inquiry into the mental process of the new Commissioner, but only into the factual questions surrounding his actions or non-action during the relevant 13-day period.

The error of the Court of Appeals herein is apparent from decisions of this Court which followed *Morgan IV*. In *United States ex rel Accardi* v. *Shaughnessy*, 347 U.S. 260 (1954), plaintiff contended upon information and belief that the Board of Immigration Appeals had ordered his deportation, not in the exercise of independent judgment, but solely at the dictation of the Attorney General of the United States. The Court rejected a presumption of regularity on behalf of the Board and thereafter a full hearing was had in the District Court at which Board members and the Attorney General testified. See *Shaughnessy* v. *United States ex rel Accardi*, 349 U.S. 280 (1955).

The second of the above *Shaughnessy* cases was expressly cited by this Court in *Citizens to Preserve Overton Park* v. *Volpe*, 401 U.S. 402 at 420 (1971). In explaining *Morgan IV*, this Court laid down the following test which petitioners respectfully submit is controlling in this case:

> "Of course, such inquiry into the mental process of administrative decision-makers is usually to be avoided . . . . And where there are administrative findings that were made at the same time as the decision . . . *there must be a strong showing of bad faith or improper behavior* before such inquiry may be made." *Id.* 401 U.S. at 420. (emphasis added)

In this case the Court of Appeals has agreed that this is a "situation where two unusual and indisputable facts, namely, the short time between Commissioner Schmidt's assumption of office and his signing the regulations here at issue, and the large number of other rules promulgated by him in the interval, create more than ordinary bases for doubt as to the extent of his personal reading and consideration." (Appendix C, *infra*, pages C5-6). 491 F.2d at 1144. It is, therefore, clear that the complaint herein constitutes a "strong showing of improper behavior"* with respect to the Commissioner's failure to comply with his personal duty. As such, the allegations in the complaint are entitled to be taken as admitted for the purpose of a motion to dismiss.

Despite this strong showing of non-compliance with his duty, the Court of Appeals establishes a different rule of law by stating: "In any event, absent *the most powerful preliminary showing* to the contrary effective government requires us to *presume* that he did." (Appendix C, *infra*, page C10). 491 F.2d at 1146. (emphasis added). Petitioners respectfully submit that a writ of certiorari should issue to review this establishment of a virtually irrebutable presumption of regularity which is contrary to the decisions of this Court. The Court of Appeals has in reality reached the line of allowing an institutional decision even where the statute designates a specific official to render the decision. This Court has expressly rejected such an approach. *Morgan I*, 298 U.S. at 481.

III. No question has been raised in this proceeding as to the sufficiency of the jurisdictional basis set forth in the complaint under 28 U.S.C. §1331(a) and §1337 (Appendix D, *infra*, page D5). Despite the availability of such jurisdiction in the District Court, the complaint

* The Court of Appeals notes there was no strong showing of bad faith. Bad faith is not an issue in this case.

was nevertheless dismissed for lack of jurisdiction because of the supposed availability of a statutory review procedure pursuant to 21 U.S.C. §371(f). (Appendix D, *infra*, page D2).

Review of the Dietary Supplement Regulations under 21 U.S.C. §371(f) is limited to an inquiry into matters appearing in the record before the Court. See also 5 U.S.C. §706. The Court of Appeals properly noted that the provision in 21 U.S.C. §371(f)(2) with respect to adducing additional evidence was related to matters dealing with the merits and not with a procedural challenge not apparent in the record. (Appendix C, *infra*, page C5). 491 F.2d at 1144. Instead, the Court of Appeals found that it had the "inherent" power to obtain evidence with respect to such a challenge. (Appendix C, *infra*, page C5). 491 F.2d at 1144.

Petitioners respectfully submit that the possibility that a Court of Appeals might choose to exercise such an inherent power does not deprive the District Court of its proper jurisdiction. Throughout this proceeding, petitioners have recognized that *evidence* of the Commissioner's failure to personally consider the record and objections will be necessary if the allegations in the complaint are ultimately to be proven. Such evidence is necessarily beyond the scope of the existing record. The statutory review procedure is neither available nor adequate within the meaning of 5 U.S.C. §703 (Appendix D, *infra*, page D4) when it is dependent on the exercise of extraordinary "inherent" fact-finding authority by a Court of Appeals.

Moreover, the availability of jurisdiction in the District Court is expressly preserved by 21 U.S.C. §371(f)(6) which makes the statutory review procedure in the Court of Appeals non-exclusive. In *Abbott Laboratories* v. *Gardner*, 387 U.S. 136 at 144-145 (1967), this Court noted that 21 U.S.C. §371(f)(6) could be applied to administra-

tive decision-making even if *not* within the scope of 21 U.S.C. §371(e) to which it logically applied. Surely, it also applies to agency action under 21 U.S.C. §371(e) where as here the logical forum for the taking of necessary evidence is in the District Court.

Finally, petitioners respectfully note that even if this Court should not grant the writ with respect to the jurisdictional issue herein, such writ should nevertheless be granted, at least with respect to the question presented by the Court of Appeals' refusal to allow the taking of evidence in the consolidated pending proceedings. (Appendix C, *infra*). Despite the interlocutory nature of such refusal, the public interest warrants an early determination by this Court of the nature of the personal duty in administrative decision-making. Unless the writ is granted, there is a danger that the Food and Drug Administration and other administrative agencies will begin to implement and apply the dastically reduced standards of personal responsibility established by the Court of Appeals.*

CONCLUSION

For the foregoing reasons, this petition for a writ of certiorari should be granted.

Respectfully submitted,

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Counsel for Petitioners.

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* Oral argument in the pending petitions in the Court of Appeals has been scheduled for June 19, 1974, and in all likelihood it will be many months before a decision is rendered on these complex regulations.

APPENDIX A

Opinion of the District Court for the Southern District of New York (Officially reported at 367 F. Supp. 889 (S. D. N. Y. 1973))

THE NATIONAL NUTRITIONAL FOODS ASSOCIATION and SOLGAR CO., INC.,

Plaintiffs,

v.

ALEXANDER M. SCHMIDT, Commissioner of Food and Drugs, and CASPAR W. WEINBERGER, Secretary of Health, Education and Welfare,

Defendants.

No. 73 Civ. 3739 (MIG).

United States District Court,
S. D. New York.
Nov. 15, 1973.

GURFEIN, District Judge:

The defendants move to dismiss the complaint pursuant to Fed. R. Civ. P. 12(b)(1) and 12(b)(6) on the grounds that the Court lacks subject matter jurisdiction and that the complaint fails to state a claim upon which relief can be granted. Alternatively, the defendants seek a protective order vacating the notice of deposition which the plaintiffs have issued to the defendant Alexander M. Schmidt, Commissioner of Food and Drugs and for a direction that such discovery not be had.

Appendix A

The plaintiff National Nutritional Foods Association ("National" is composed of business concerns located in New York State and throughout the United States and includes manufacturers, wholesalers, and retailers of vitamins and dietary supplements. Plaintiff Solgar Co. Inc. ("Solgar"), a member of National, is a New York corporation with its principal place of business in Manhattan and engages in the manufacture, distribution and sale in interstate commerce of vitamins and dietary supplements.

The defendant Casper W. Weinberger is Secretary of Health, Education and Welfare ("Secretary") and is authorized to issue regulations pursuant to 21 U.S.C. §371 under the Federal Food, Drug and Cosmetic Act. The defendant Alexander M. Schmidt is Commissioner of Food and Drugs ("Commissioner"), to whom the Secretary has delegated his authority to promulgate such regulations.

National and Solgar have filed a complaint, 73 Civ. 3739, seeking (a) preliminary and permanent injunctions enjoining and restraining the defendants from enforcing certain regulations relating to the labeling and content of dietary supplements and (b) a mandatory injunction directing the Commissioner "to properly consider, review and evaluate the record before him" in connection with the regulations described and "to publish his findings of fact and conclusions of law."

Federal jurisdiction is found under 28 U.S.C. §§1331 (a) and 1337. The matter in controversy arises under the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §301 et seq. and also the Administrative Procedure Act, 5

U.S.C. §551 et seq. The complaint alleges that this action is authorized by 5 U.S.C. §§702-706. Venue purportedly lies here by virtue of 28 U.S.C. §1391(e)4.

The complaint attacks the promulgation by the Commissioner of certain portions of the Dietary Supplement Regulations which were published in 38 Fed. Reg. 20708-20718, 20730-20740 (1973). The plaintiffs allege that the promulgation was not in accordance with the requisite procedural requirements.

FACTS: *Procedural History of the Challenged Regulations*

The parties agree about most of the essential facts. The regulatory scheme here attacked finds its inception with a notice of proposed rule-making published in 27 Fed. Reg. 5815 (1962). Numerous comments were received in response to this notice. In June 1966, orders were subsequently promulgated establishing definitions and standards of identity for dietary supplements of vitamins and minerals and revising the regulations for labeling of food for special dietary uses. 37 Fed. Reg. 8521 et seq. (1966). Objections to these orders and requests for a public hearing were filed. After issuing a stay of the effective date of the June 1966 order (31 Fed. Reg. 15730 (1966)) public hearings commenced on June 20, 1968 and concluded nearly two years later on May 14, 1970. The transcript of the hearings comprises over 32,000 pages of testimony plus additional thousands of pages of documentary exhibits.

The hearing examiner who presided over the two years of hearings submitted his report to the Commissioner on January 25, 1971.

Appendix A

On January 19, 1973 the Commissioner—who was then Charles C. Edwards—published proposed findings of fact, proposed conclusions of law and tenative orders. 38 Fed. Reg. 2143-2150 and 38 Fed. Reg. 2152-2162. These orders permitted those who appeared at the hearing to file written exceptions within 60 days, which was subsequently extended to April 20, 1973. (38 Fed. Reg. 6396 (1973)). Exceptions to the orders and findings were filed by 35 persons who had appeared at the hearing, consisting of over 1,000 pages, and approximately 20,000 additional letters.

Shortly before the expiration date for exceptions to be filed, Commissioner Edwards resigned his position on April 6, 1973.

On July 12, 1973 the defendant Schmidt was sworn in as Commissioner of Food and Drugs. On August 2, 1973 the final findings of fact, conclusion of law and orders were published in the Federal Register, 38 Fed. Reg. 20768-20718, 20730-20740 (1973). Included in the August 2 promulgation was the Commissioner's statement:

> "Having considered the evidence received at the hearing, the hearing examiner's report, and all the exceptions and written arguments which were filed, the Commissioner, pursuant to the Federal Food, Drug, and Cosmetic Act (secs. 201(n), 401, 403(a) and (j), 701(a) and (e), 52 Stat. 1046, 1048, 1055, 1056, as amended by 70 Stat. 919; 21 U.S.C. 321 (n), 341, 343(a) and (j), 371(a) and (e)) and under authority delegated to him (21 CFR 2.120), issues the following Findings of Fact, Conclusions, and Final Order. . . ." (38 Fed. Reg. 20712, 20734)

Appendix A

The regulations at issue are complex, technical and interrelated but for purposes of this motion it is only necessary to summarize their purpose and effect.*

The two groups of regulations involved here, Part 80 and Part 125 of 21 CFR, provide for labeling which will identify the nature of the product being purchased and its nutritional value. These regulations are part of a coordinated package of 19 regulations, proposals, and policy directives designed to govern the definition, identity, formulation and promotion of vitamin and mineral products.

Pursuant to 21 U.S.C. §341, the regulations of Part 80 establish definitions and standards of identity for dietary supplements of vitamins and minerals and for vitamin and mineral foods. These regulations, under statutory authority to issue such regulations as will promote honesty and fair dealing in the interest of consumers, are designed to facilitate consumer understanding as to the composition of vitamin and mineral products which are represented to be of special dietary use to supplement the diet by increasing the dietary intake of vitamins or minerals or both.

The new provisions of Part 125, pursuant to authority granted in 21 U.S.C. §343(j), revised the regulations governing the labeling of food for special dietary uses. Section 343(j) deems a food to be misbranded if it purports to be or is represented for special dietary uses, unless its label supplies information necessary to inform purchasers as to its value for such uses. Due to the

* The Commissioner recently ordered a stay of the effective date for ordering new labeling pending the outcome of judicial review. The effective date for the use of new labeling remains December 31, 1974. 38 Fed. Reg. 29577 (Oct. 26, 1973)

complexity of conventional food supply the regulation requires the labeling of a food for special dietary use to indicate clearly to the consumer the ingredients of significant value and need in human nutrition and the proportion of such ingredients. This indication is to be achieved through the use of a simplified unit of measurement—the Recommended Daily Allowance (RDA).

Briefly summarized, the purpose and effect of these two regulations is to require full and honest labeling and the fair promotion of vitamin and mineral products as the basis for a more informed consumer choice, while leaving the basic responsibility for deciding personal nutritional practices to the consumer himself. The regulations define the term "special dietary use." They establish the U.S. Recommended Daily Allowance (U.S. RDA) to replace the former Minimum Daily Requirement (M.D.R.) as the official measurement of nutritional intake. They specify the U.S. RDA for various vitamins and minerals for infants, children under four years of age, adults and children over four years of age, and pregnant or lactating women. The regulations draw a distinction between ordinary food, special dietary foods intended for diet supplementation, and drugs intended for the treatment of disease.

The plaintiffs contend that it was physically impossible for the Commissioner to have reviewed and considered the record prior to signing the Dietary Supplement Regulations into effect, and that the Commissioner did not act and could not have acted in the exercise of considered independent judgment when he promulgated these regulations. The plaintiffs point to the fact that the Commissioner signed the Dietary Supplement Regulations only thirteen (13) days after his appointment, although

the matter had been under agency consideration for eleven years and the record consisted of 32,000 pages of transcript plus thousands of pages of documentary exhibits. Moreover, during that same period the Commissioner signed and caused to be published at least 33 items comprising 14 final regulations, 13 proposed regulations and six notices (including the two final orders at issue here).

MOTION TO DISMISS

The defendants move to dismiss pursuant to Fed. R. Civ. P. 12(b)(6) and 12(b)(1) on the grounds that the complaint does not state a claim upon which relief can be granted and because this court lacks jurisdiction.

[1, 2] The defendants argue that the plaintiff's sole recourse for review of the orders promulgating the Dietary Regulations is on review by a Circuit Court of Appeals. Before we can consider the merits, we must first determine whether the District Court has jurisdiction in this situation, or whether jurisdiction is exclusive in the Court of Appeals under 21 U.S.C. §371(f). There is no doubt that the Dietary Regulations here challenged were promulgated pursuant to 21 U.S.C. §371(e). Review of §371(e) orders is generally in the Court of Appeals, pursuant to §371(f)(1), and is subject to the "substantial evidence" criterion of §371(f)(3). If the action was taken by the Commissioner outside of the requirements of Section 371 (e)—as, for example, where there has been no hearing, the District Court would have jurisdiction. Abbott Laboratories v. Gardner, 387 U.S. 136, 87 S.Ct. 1507, 18 L.Ed.2d 681 (1967). Such jurisdiction is based on the Administrative Procedure Act §10 (5 U.S.C. §§702-706), and on the saving clause of the Food and Drug Act as construed in *Abbott*, supra. Section 371(f)(6) itself provides: "The remedies provided for in this subsection shall be in addi-

tion to and not in substitution for any other remedies provided by law."

The attack here is on "the validity" of the regulations, but the specific ground of attack is an alleged failure to comply with the procedural requirement of personal consideration of the evidence by the Commissioner himself. Since the attack is not upon the record made, but on whether the Commissioner read it, the appellate review provided in §371(f)(1) is said to be inadequate. It is contended by the plaintiffs that the Court of Appeals, reviewing under §371(f)(1), would be limited to the record as made. They contend further that if the plaintiffs wish to adduce additional evidence before the Court of Appeals, that court would be limited, under Section 371(f)(2) "[to] order such additional evidence to be taken before the Secretary"—which in this case, it is said, would be self-defeating.

We may note also that the former Section 10(b) of the Administrative Procedure Act, now 5 U.S.C. §703 provides in pertinent part:

> "The form of proceeding for judicial review is the special statutory review proceeding relevant to the subject matter in a court specified by statute or, *in the absence or inadequacy thereof*, any applicable form of legal action, including actions for declaratory judgments or writs of prohibitory or mandatory injunction or habeas corpus, in a court of competent jurisdiction. . . ." (Emphasis supplied).

[3] The real issue of jurisdiction is whether the review procedure in the Court of Appeals would be "inadequate." There is a dearth of authority directly on the point.

It should be noted that the issue presented in *Abbott*, supra, was not whether jurisdiction was in the Court of

Appeals or the District Court, but whether, if it was not in the District Court, there was any judicial review whatever. *Abbott* is, therefore, not of direct aid.

The type of procedural attack here launched has actually been the subject of review by a distinguished Court of Appeals. In Braniff Airways, Inc. v. C.A.B., 126 U.S.App. D.C. 399, 379 F.2d 453 (1967), on a statutory review of a CAB order in an adjudicatory proceeding, the Court of Appeals reviewed claims that 1. there was no quorum of the Board present on the critical dates; 2. the order was not valid because it did not become "effective" until after a Board member had resigned; and 3. the "notation practice," under which the views and votes of the members are recorded separately, rather than in joint session, and circulated to the remaining members was invalid. The Court was able to determine all these procedural matters on the merits. And I see no distinction in this regard between the review of an adjudicatory determination by an agency and the review of the promulgation of a regulation after a hearing.

The only thing that gives me pause with respect to the "adequacy" of Court of Appeals review is Judge Friendly's comment, in another context, that "a district court may be in a better position than a court of appeals to carry out fact finding." See Toilet Goods Ass'n v. Gardner, 360 F.2d 677, 684, n. 8 (2 Cir. 1966), aff'd, 387 U.S. 158, 167, 87 S.Ct. 1520, 18 L.Ed.2d 697 (1967).

I do not believe, however, that fact finding will be required here. If the Court of Appeals should hold that the plaintiffs are entitled to make a case on the facts relating to the Commissioner's procedures, it can appoint a Special Master under its equity powers. See generally, Polish National Alliance of the United States of North America

v. N.L.R.B., 159 F.2d38 (7 Cir. 1946); N.L.R.B. v. Remington Rand, Inc., 130 F.2d 919 (2 Cir. 1942); N.L.R.B. v. Arcade-Sunshine Co., 76 U.S.App.D.C. 312, 132 F.2d 8 (D.C.Cir. 1942); Olson Rug Co. v. N.L.R.B., 304 F.2d 710 (7 Cir. 1962).

If the Court of Appeals should require no further "facts," it can issue a mandatory injunction to the Commissioner to review and evaluate the record, as the plaintiff prays. See Twin City Milk Producers Ass'n v. McNutt, 122 F.2d 564 (8 Cir. 1941).

[4, 5] If, as I think more likely, the court should hold, as a matter of law, that the plaintiffs have no right to go behind the Commissioner's affirmative finding, that would dispose of the matter.[1]

I cannot find, therefore, that review by the Court of Appeals in this matter would be "inadequate." I, therefore, hold that since the determination was made under §371(e), review may be had only under §371(f), by a Court of Appeals.

The complaint is accordingly dismissed.

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[1] While under proper circumstances an allegation of failure to comply with proper procedures may constitute a valid due process claim, cf. R. H. Macy & Co. v. Tinley, 249 F.Supp. 778, 782 (D.C. 1966), the mere suppositional allegation made here does not, in my opinion, state such a claim. See Twin City Milk Producers Ass'n v. McNutt, 122 F.2d 564, 569 (8 Cir. 1941). The Commissioner's actions are clothed in a presumption of regularity. Braniff Airways, Inc., supra; Willapoint Oysters v. Ewing, 174 F.2d 676, 696 (9 Cir.), cert. denied, 338 U.S. 860 (1950). And the Commissioner should not be subjected to direct questioning on the manner or extent of his study of the record. See Morgan v. United States, 313 U.S. 409, 421-22 (1941). This case is unlike United States ex rel. Shaughnessy v. Accardi, 347 U.S. 260, 74 S.Ct. 499, 98 L.Ed. 681 (1954) where there was a finding of sufficient allegation of undue influence by the Attorney General on the Board of Immigration Appeals; see 379 U.S. 280, 282 (1955).

APPENDIX B

Order of the United States Court of Appeals for the Second Circuit

C 41
74-1225

UNITED STATES COURT OF APPEALS
SECOND CIRCUIT

At a Stated Term of the United States Court of Appeals, in and for the Second Circuit, held at the United States Court House, in the City of New York, on the 26th day of March, one thousand nine hundred and 74

THE NATIONAL NUTRITIONAL FOODS ASSOCIATION and SOLGAR CO., INC.,
Plaintiffs-Appellants,

v.

ALEXANDER M. SCHMIDT, Commissioner of Food and Drugs, and CASPER W. WEINBERGER, Secretary of Health, Education and Welfare,
Defendants-Appellees.

It is hereby ordered that in response to the motion made herein by counsel for the appellants, the judgment of the district court is summarily affirmed.

It is further ordered that the Government's cross motion for consolidation is dismissed as moot.

LEONARD P. MOORE
Leonard P. Moore
HENRY J. FRIENDLY
Henry J. Friendly
ROBERT P. ANDERSON
Robert P. Anderson
Circuit Judges

APPENDIX C

Opinion of the United States Court of Appeals for the Second Circuit (Officially reported at 491 F. 2d 1141 (2d Cir., 1973))

UNITED STATES COURT OF APPEALS

FOR THE SECOND CIRCUIT

September Term, 1973.

(Submitted January 15, 1974 Decided February 1, 1974.)

Docket No. 73-2129

NATIONAL NUTRITIONAL FOODS ASSOCIATION and SOLGAR CO., INC.,

Petitioners,

v.

FOOD AND DRUG ADMINISTRATION, UNITED STATES DEPARTMENT OF HEALTH, EDUCATION AND WELFARE,

Respondent.

Before:

MOORE, FRIENDLY and ANDERSON,

Circuit Judges.

FRIENDLY, *Circuit Judge*:

This motion is made in one of fifteen petitions to review two orders of the Food and Drug Administration (FDA) signed by Alexander M. Schmidt, Commissioner of

Food and Drugs, on July 25, 1973, and published in the Federal Register on August 2, 1973. These orders added to 21 C.F.R. Part 80—Definitions and Standards of Identity for Food for Special Dietary Uses, 38 F.R. 20730-40, and revised Part 125—Label Statements Concerning Dietary Properties of Food Purporting to Be or Represented for Special Dietary Uses, 38 F.R. 20708-18. These voluminous regulations, fully effective December 31, 1974, are the end-product of a Notice of Proposal To Revise Regulations published in 1962, 27 F.R. 585. The final phase began with a notice of public hearing in 1968, 33 F.R. 8679; the hearings lasted for almost two years and produced over 32,000 pages of testimony and thousands of pages of exhibits. Each set of regulations is preceded by several pages of comment (hereafter the preamble) in which the exceptions are summarized and reasons are given for their rejection or adoption. The petitions to review, filed in this Circuit and in the Ninth and District of Columbia Circuit, have all found their way to this court under 28 U.S.C. §2112(a) and have been consolidated.

The basis for the instant motion to take the deposition of Commissioner Schmidt and for related relief or to appoint a special master to achieve similar ends is as follows: Tentative final orders signed by Charles C. Edwards, then Commissioner of Food and Drugs, were published in January, 1973, 38 F.R. 2143-50, 2152-62; the time for filing exceptions expired on April 20, 1973. Meanwhile Commissioner Edwards had resigned. The formal exceptions spread over 1,000 pages; there were 20,000 additional letters. Commissioner Schmidt took office on July 12, 1973. During the 13-day period ending with the signing of the orders here under review, he signed and caused to be published 14 final regulations, 13 proposed regula-

tions and 6 notices stretching over many pages of the Federal Register, many of which deal with the composition or labelling of food products.[1] The final regulations here at issue contain a recital that the Commissioner had "considered the evidence received at the hearing, the hearing examiner's report, and all the exceptions and written arguments which were filed . . ." 38 F.R. at 20712; *see id.* at 20734. The relevant statute, 21 U.S.C. §371(e)(3), directs that after the prescribed procedures for hearing and objections, the Secretary of Health, Education and Welfare, whose powers have been delegated to the Commissioner of Food and Drugs, 21 C.F.R. §§2.68-2.98, "shall by order act upon such objections and make such order public."

In an effort to develop that it was physically impossible for the new Commissioner to have reviewed and considered the objections prior to signing the orders here at issue, the petitioners instituted an action against him in the District Court for the Southern District of New York. Judge Gurfein dismissed this for lack of jurisdiction. He noted that, as the parties agreed, under 21 U.S.C. §371(f) jurisdiction to review the orders lay in the courts of appeals. Plaintiffs contended, however, that a court of appeals could not take additional evidence before itself both because §371(f)(2) empowers the court of appeals, when a petitioner applies for leave to adduce additional evidence and makes a proper showing, only to

[1] Examples are Amino Acids in Food for Human Consumption, dated July 19, 1973, 38 F.R. 20036-39, and Standards of Quality for Foods for Which There Are No Standards of Identity, dated July 25, 1973, 38 F.R. 20726-30. Others deal with unrelated problems, e.g., Ch. 1, Part 273, Additional Standards for Source Plasma (Human) Used in Preparation of Blood Derivatives Intended for Injection, dated July 17, 1973, 38 F.R. 19362-68.

"order such additional evidence . . . to be taken before the Secretary" which would be manifestly inappropriate here, and because its collegial nature makes a court of appeals institutionally ill-adapted to take evidence itself. From the premise thus thought to be established, plaintiffs reasoned that, under §9(b) of the Administrative Procedure Act, now 5 U.S.C. §703, "the special statutory review proceeding" was inadequate for their immediate needs and an action lay in the district court. Judge Gurfein rejected both branches of plaintiffs' premise largely on the authority of *Braniff Airways, Inc.* v. *C.A.B.*, 379 F.2d 453 (D.C. Cir. 1967), where the court of appeals had obtained, apparently without objection, extra-record material relating to the internal processes of the Civil Aeronautics Board relevant to the claims of procedural irregularity raised before it. He further noted, with respect to the claim of institutional inadequacy on the part of the court of appeals, that this court could appoint a special master, citing a number of contempt proceedings for violations of orders of the Labor Board.[2]

The *Braniff* case may not be quite so authoritative as the district judge thought, since the Federal Aviation Act, 49 U.S.C. §1486, contains no express provision for the

[2] The district judge stated that the only thing which gave him pause was a remark by the writer in *Toilet Goods Ass'n* v. *Gardner*, 360 F.2d 677, 684 n.8 (2 Cir. 1966), *aff'd*, 387 U.S. 158, 167 (1967), that in the review of rules "a district court may be in a better position than a court of appeals to carry out fact finding . . ." We agree that this afforded no ground for a different decision. The comment was made with respect to rules not protected by the usual provisions making findings supported by substantial evidence conclusive and limiting the production of new evidence. Both sides in the *Toilet Goods* case contemplated a trial if the Government's motion to dismiss were not granted.

taking of additional evidence, although it probably would be construed to require this to be taken before the Civil Aeronautics Board if taken at all. We nevertheless are in complete agreement with the court's rejection of petitioners' premise. The provision in 21 U.S.C. §371(f)(2) that additional evidence shall be taken before the Secretary refers to evidence that might alter his determination on the merits and for that reason should be taken before him—not to evidence that, because of procedural irregularity, his determination was a nullity. A reviewing court has inherent power to obtain evidence needed to enable it to decide a contention of this sort. The difficulties in a court of appeals' informing itself with respect to such a matter are imaginary. There is nothing to prevent the hearing of evidence by three judges, as sometimes occurs in courts convoked under 28 U.S.C. §§2281 and 2282, cumbersome though it be.[3] Apart from the possibility of appointing a special master, an alternate form of relief sought here by petitioners, the evidence desired could doubtless be obtained by deposition, as petitioners primarily propose. We thus entertain no doubt of our power to grant petitioners' motion.

Conceding that it is not the function of this court "to probe the mental processes" of the Commissioner, *Morgan* v. *United States*, 304 U.S. 1, 18 (1938) (*Morgan II*), petitioners insist they are entitled to probe whether he exercised his own mental processes at all. More particularly, they claim they are entitled to do this in a situation where

[3] Indeed evidence was taken before a court of three judges in *Morgan* v. *United States*, 23 F. Supp. 380 (W.D. Mo. 1937), after the remand in 298 U.S. 468 (1936), on which petitioners so heavily rely. It was done so again in the proceeding leading to *Morgan IV*, *see* 32 F. Supp. 546 (W.D. Mo. 1940).

two unusual and indisputable facts, namely, the short time between Commissioner Schmidt's assumption of office and his signing of the regulations here at issue, and the large number of other rules promulgated by him in the interval, create more than ordinary basis for doubt as to the extent of his personal reading and consideration.

It is plain enough that if this motion had come before us in the period between the first *Morgan* case, *Morgan* v. *United States*, 298 U.S. 468, 481 (1936), holding that in administrative proceedings "The one who decides must hear" and that a court seized of a review proceeding must inquire whether he had, and the fourth and last appearance of the *Morgan* case in the Supreme Court, *United States* v. *Morgan*, 313 U.S. 409 (1941), we would have been obliged to grant it. But the life of this aspect of *Morgan* I was extremely brief. In *Morgan IV* Mr. Justice Frankfurter, writing for a Court unanimous on this point,[4] took back most or all of what the first decision had given, 313 U.S. at 421-22. *Morgan IV* dealt with a proceeding wherein the Secretary of Agriculture had fixed rates for the Kansas City stockyards that would govern distribution of funds impounded during the long pendency of the litigation. Upon a challenge to the extent of the Secretary's participation in the making of these rates similar to that which had been made in *Morgan I*, the district court had taken his testimony as the Court had directed in *Morgan I*. After strongly suggesting that it would reject on the merits a challenge with respect to the degree of the Secretary's personal consideration, the Court went on

[4] Mr. Justice Roberts dissented on another issue. Chief Justice Hughes, the author of *Morgan I*, concurred in Mr. Justice Frankfurter's opinion.

to hold: "But the short of the business is that the Secretary should never have been subjected to this examination." 313 U.S. at 422. Professor Kenneth Culp Davis has correctly characterized this, 2 Administrative Law Treatise §11.05, at 59 (1958), as a return to the law declared in *De Cambra* v. *Rogers*, 189 U.S. 119, 122 (1903):

> It is hardly necessary to say that when a decision has been made by the Secretary of the Interior, courts will not entertain an inquiry as to the extent of his investigation and knowledge of the points decided, or as to the methods by which he reached his determination.

Subsequent Supreme Court decisions have not detracted from the force of *Morgan IV*. Petitioners rely on *United States ex rel. Accardi* v. *Shaughnessy*, 347 U.S. 260 (1954), *see also Shaughnessy* v. *United States ex rel. Accardi*, 349 U.S. 280 (1955), but the charge there thought to require the taking of evidence was that the agency to which discretion had been given, the Board of Immigration Appeals, had acted at the dictation of the Attorney General; indeed, the case is questionable authority for the taking of testimony even on its own facts. *See* 2 Davis, *supra*, §11.05, at 61 n.10. They press even more strongly a portion of Mr. Justice Marshall's opinion in *Citizens to Preserve Overton Park, Inc.* v. *Volpe*, 401 U.S. 402, 420 (1971), stating that on remand the district court "may require the administrative officials who participated in the decision to give testimony explaining their action." But *Overton Park* was a case where the Secretary of Transportation had made no formal findings; the taking of testimony, suggested as being within the range of proper action for the district court on remand, was for the purpose of

ascertaining why the highway construction had been authorized, a function performed by the extensive preambles to the regulations here at issue. The Court reaffirmed *Morgan IV*, saying that where findings accompany the decision, "there must be a strong showing of bad faith or improper behavior" before testimony with regard to reasons can be taken. *Id.* Indeed, the opinion went on to say that testimony might not be required even in *Overton Park* if the Secretary could prepare *post hoc* findings sufficient to withstand scrutiny. *Id.* at 420-21. Nothing in the opinion suggests that the Court intended to allow inquiry into the relative participation of the Secretary and his subordinates.[5] Similarly, strong preliminary showings of bad faith have been required in the court of appeals cases cited by petitioners before the taking of testimony has been permitted with regard to internal agency deliberations. *See, e.g., Singer Sewing Machine Co.* v. *NLRB*, 329 F.2d 200, 206-08 (4th Cir. 1964).

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[5] The difficulties of such an inquiry are illustrated by Mr. Justice Blackmun's concurrence, 401 U.S. at 422-23, pointing out that the case was "the end product of more than a decade of endeavor to solve the interstate highway problem at Memphis" and that the "administrative decisions under attack here are not those of a single Secretary; some were made by the present Secretary's predecessor and, before him, by the Department of Commerce's Bureau of Public Roads."

The statement in *Overton Park* that the district court could take testimony as to reasons was extended by *Camp* v. *Pitts*, 411 U.S. 138, 142-43 (1973) (*per curiam*), arising under the National Bank Act, from cases in which the agency has made no findings to those where its "stated justification for informal action does not provide an adequate basis for judicial review." *Id.* at 138. But *Pitts* no more than *Overton Park* suggests that inquiry will be permitted into relative participation in the decision by various agency personnel.

Appendix C

The facts of this case do not constitute nearly the showing of bad faith necessary to justify further inquiry; indeed they vividly illustrate the necessity of adhering to the presumption of regularity with respect to the participation of the officer authorized to sign administrative orders, especially in the context of the promulgation of legislative rules as distinguished from adjudication. As stated, the regulations here at issue are the end-product of more than a decade of work by the FDA. Petitioners do not contest that predecessors of Commissioner Schmidt, notably Commissioner Edwards, took an active part in the development of the regulations. All would have been well, apparently, if Commissioner Edwards had continued to serve. But because he resigned in April 1973 and Commissioner Schmidt did not take office until mid-July, promulgation must wait until the new Commissioner could personally familiarize himself with 1,000 pages of formal exceptions, 20,000 letters, and the staff's views about them, and read the relevant portions of the record (or summaries of them). And the same must be true of all the other regulations awaiting the new Commissioner's signature. With the enormous increase in delegation of lawmaking power which Congress has been obliged to make to agencies, both independent and in the executive branch, and in the complexity of life, government would become impossible if courts were to insist on anything of the sort. It would suffice under the circumstances that Commissioner Schmidt considered the summaries of the objections and of the answer contained in the elaborate preambles and conferred with his staff about them. There is no reason why he could not have done this even in the limited time available, *cf. Twin City Milk Producers Ass'n* v. *McNutt*, 122 F.2d 564, 568-69 (8 Cir. 1941); *Florida Economic Advisory Council* v. *F.P.C.*, 251 F.2d 643, 648 (D.C. Cir. 1957)

(Burger, *J.*), *cert. denied*, 356 U.S. 959 (1958), although we do not envy him the task.[6] In any event, absent the most powerful preliminary showing to the contrary, effective government requires us to presume that he did. It was his special insight into the workings of the administrative process, as it was and might become, that enabled Mr. Justice Frankfurter in *Morgan IV* to persuade the Court to retreat from *Morgan I*.[7] This is no time for an attempt to regain territory so wisely yielded.

The motion to take the testimony of the Commissioner and to have other discovery, or for the appointment of a master, is denied.

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[6] It should be noted that the demands on the Commissioner's time during the 13 days preceding the signing of these orders are somewhat exaggerated by the observation, stressed by petitioners and mentioned above, that in that period he signed and caused to be published 14 final regulations, 13 proposed regulations, and 6 notices. Although 21 U.S.C. § 371, for example, speaks in terms of action by the Secretary (and by delegation the Commissioner, 21 C.F.R. §§ 2.68-2.98) throughout the process of proposal and promulgation of many types of regulations with respect to food and drugs, nevertheless whatever remains of the *Morgan I* requirement that "The one who decides must hear" surely applies to the one who *ultimately* decides. Compare *Opp Cotton Mills, Inc.* v. *Administrator*, 312 U.S. 126, 152-53, *modified*, 312 U.S. 657 (1941). A spot check of the published items other than final regulations signed by Commissioner Schmidt between July 12 and July 25, 1973 reveals only the most limited assertions of a personal role. *See, e.g.*, Filled Milk Products: Proposed Common or Usual Name, dated July 25, 1973, 38 F.R. 20748-49; Ophthalmic Drugs Advisory Committee: Notice of Meeting, dated July 18, 1973, 38 F.R. 19850-51.

[7] Very shortly after *Morgan I*, a perceptive commentator had pointed out that, despite its seeming "so eminently reasonable on its face," the decision probably would require the Secretary of Agriculture "to devote all his time to the conduct of matters which must be considered petty from a national viewpoint." A. H. Feller, Prospectus for the Further Study of Federal Administrative Law, 47 Yale L.J. 647, 662 (1938).

APPENDIX D

Statutes

21 U.S.C. §371. (Federal Food, Drug and Cosmetic Act)

(e) (1) Any action for the issuance, amendment, or repeal of any regulation under section 341, 343(j), 344(a), 346, 351(b), or 352(d) or (h), of this title shall be begun by a proposal made (A) by the Secretary on his own initiative, or (B) by petition of any interested person, showing reasonable grounds therefor, filed with the Secretary. The Secretary shall publish such proposal and shall afford all interested persons an opportunity to present their views thereon, orally or in writing. As soon as practicable thereafter, the Secretary shall by order act upon such proposal and shall make such order public. Except as provided in paragraph (2) of this subsection, the order shall become effective at such time as may be specified therein, but not prior to the day following the last day on which objections may be filed under such paragraph.

(2) On or before the thirtieth day after the date on which an order entered under paragraph (1) of this subsection is made public, any person who will be adversely affected by such order if placed in effect may file objections thereto with the Secretary, specifying with particularity the provisions of the order deemed objectionable, stating the grounds therefor, and requesting a public hearing upon such objections. Until final action upon such objections is taken by the Secretary under paragraph (3) of this subsection, the filing of such objections shall operate to stay the effectiveness of those provisions of the order to which the objections are made. As soon as practicable after the time for filing objections has expired the Secretary shall publish a notice in the Federal Register specifying those parts of the order which have been stayed by the

filing of objections and, if no objections have been filed, stating that fact.

(3) As soon as practicable after such request for a public hearing, the Secretary, after due notice, shall hold such a public hearing for the purpose of receiving evidence relevant and material to the issues raised by such objections. At the hearing, any interested person may be heard in person or by representative. As soon as practicable after completion of the hearing, the Secretary shall by order act upon such objections and make such order public. Such order shall be based only on substantial evidence of record at such hearing and shall set forth, as part of the order, detailed findings of fact on which the order is based. The Secretary shall specify in the order the date on which it shall take effect, except that it shall not be made to take effect prior to the ninetieth day after its publication unless the Secretary finds that emergency conditions exist necessitating an earlier effective date, in which event the Secretary shall specify in the order his findings as to such conditions.

Review of order

(f) (1) In a case of actual controversy as to the validity of any order under subsection (e) of this section, any person who will be adversely affected by such order if placed in effect may at any time prior to the ninetieth day after such order is issued file a petition with the United States court of appeals for the circuit wherein such person resides or has his principal place of business, for a judicial review of such order. A copy of the petition shall be forthwith transmitted by the clerk of the court to the Secretary or other officer designated by him for that purpose. The Secretary thereupon shall file in the court the record of

the proceedings on which the Secretary based his order, as provided in section 2112 of Title 28.

(2) If the petitioner applies to the court for leave to adduce additional evidence, and shows to the satisfaction of the court that such additional evidence is material and that there were reasonable grounds for the failure to adduce such evidence in the proceeding before the Secretary, the court may order such additional evidence (and evidence in rebuttal thereof) to be taken before the Secretary, and to be adduced upon the hearing, in such manner and upon such terms and conditions as to the court may seem proper. The Secretary may modify his findings as to the facts, or make new findings, by reason of the additional evidence so taken, and he shall file such modified or new findings, and his recommendation, if any, for the modification or setting aside of his original order, with the return of such additional evidence.

(3) Upon the filing of the petition referred to in paragraph (1) of this subsection, the court shall have jurisdiction to affirm the order, or to set it aside in whole or in part, temporarily or permanently. If the order of the Secretary refuses to issue, amend, or repeal a regulation and such order is not in accordance with law the court shall by its judgment order the Secretary to take action, with respect to such regulation, in accordance with law. The findings of the Secretary as to the facts, if supported by substantial evidence, shall be conclusive.

(4) The judgment of the court affirming or setting aside, in whole or in part, any such order of the Secretary shall be final, subject to review by the Supreme Court of the United States upon certiorari or certification as provided in sections 346 and 347 of Title 28.

(5) Any action instituted under this subsection shall survive notwithstanding any change in the person occupying the office of Secretary or any vacancy in such office.

(6) The remedies provided for in this subsection shall be in addition to and not in substitution for any other remedies provided by law.

5 U.S.C. §703. (Administrative Procedure Act)

The form of proceeding for judicial review is the special statutory review proceeding relevant to the subject matter in a court specified by statute or, in the absence or inadequacy thereof, any applicable form of legal action, including actions for declaratory judgments or writs of prohibitory or mandatory injunction or habeas corpus, in a court of competent jurisdiction. Except to the extent that prior, adequate, and exclusive opportunity for judicial review is provided by law, agency action is subject to judicial review in civil or criminal proceedings for judicial enforcement.

5 U.S.C. §706. (Administrative Procedure Act)

To the extent necessary to decision and when presented, the reviewing court shall decide all relevant questions of law, interpret constitutional and satutory provisions, and determine the meaning or applicability of the terms of an agency action. The reviewing court shall—

(1) compel agency action unlawfully withheld or unreasonably delayed; and

(2) hold unlawful and set aside agency action, findings, and conclusions found to be—

(A) arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law;

(B) contrary to constitutional right, power, privilege, or immunity;

(C) in excess of statutory jurisdiction, authority, or limitations, or short of statutory right;

(D) without observance of procedure required by law;

(E) unsupported by substantial evidence in a case subject to sections 556 and 557 of this title or otherwise reviewed on the record of an agency hearing provided by statute; or

(F) unwarranted by the facts to the extent that the facts are subject to trial de novo by the reviewing court.

In making the foregoing determinations, the court shall review the whole record or those parts of it cited by a party, and due account shall be taken of the rule of prejudicial error.

28 U.S.C. §1331.

(a) The district courts shall have original jurisdiction of all civil actions wherein the matter in controversy exceeds the sum or value of $10,000, exclusive of interest and costs, and arises under the Constitution, laws, or treaties of the United States.

28 U.S.C. §1337.

The district courts shall have original jurisdiction of any civil action or proceeding arising under any Act of Congress regulating commerce or protecting trade and commerce against restraints and monopolies. June 25, 1948, c. 646, 62 Stat. 931.